

Exhibit B

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

In re: National Prescription Opiate Litigation

Plaintiff

v.

Defendant

Civil Action No. 1:17-md-02804-DAP

(If the action is pending in another district, state where:)

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Drug Enforcement Administration, 8701 Morrisette Dr., Springfield, VA 22152

☒ **Testimony:** **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization that is *not* a party in this case, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

See Schedule A.

Place: Williams & Connolly, LLP
725 Twelfth St. NW, Washington, D.C. 20005

Date and Time:

9:00AM, 08/21/2018

The deposition will be recorded by this method: Stenographic and/or by video and audio recording

- ☐ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and permit their inspection, copying, testing, or sampling of the material:

The provisions of Fed. R. Civ. P. 45(c), relating to your protection as a person subject to a subpoena, and Rule 45 (d) and (e), relating to your duty to respond to this subpoena and the potential consequences of not doing so, are attached.

Date: 07/10/2018

SANDY OPACICH, CLERK OF COURT

OR

*Signature of Clerk or Deputy Clerk**/s/ Enu Mainigi**Attorney's signature*

The name, address, e-mail, and telephone number of the attorney representing (name of party)

All Defendants, who issues or requests this subpoena, are:

Enu Mainigi, 725 Twelfth St. NW, Washington, DC 20005, emainigi@wc.com, 202-434-5000

AO 88A (Rev. 06/09) Subpoena to Testify at a Deposition in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

This subpoena for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

☐ I served the subpoena by delivering a copy to the named individual as follows: _____
_____ on *(date)* _____; or

☐ I returned the subpoena unexecuted because: _____
_____.

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Federal Rule of Civil Procedure 45 (c), (d), and (e) (Effective 12/1/07)**(c) Protecting a Person Subject to a Subpoena.**

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction — which may include lost earnings and reasonable attorney's fees — on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing or sampling any or all of the materials or to inspecting the premises — or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the issuing court for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) When Required. On timely motion, the issuing court must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person who is neither a party nor a party's officer to travel more than 100 miles from where that person resides, is employed, or regularly transacts business in person — except that, subject to Rule 45(c)(3)(B)(iii), the person may be commanded to attend a trial by traveling from any such place within the state where the trial is held;

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) When Permitted. To protect a person subject to or affected by a subpoena, the issuing court may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information;

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party; or

(iii) a person who is neither a party nor a party's officer to incur substantial expense to travel more than 100 miles to attend trial.

(C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(c)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(d) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information to the court under seal for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(e) Contempt. The issuing court may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena. A nonparty's failure to obey must be excused if the subpoena purports to require the nonparty to attend or produce at a place outside the limits of Rule 45(c)(3)(A)(ii).

SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below. Other terms shall have their plain meaning.

1. “You” and “Your” refers to the Drug Enforcement Administration (“DEA”) and all others acting or purporting to act on DEA’s behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
2. “Communication” means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
3. “Defendants” means all defendants named in *In re National Prescription Opiate Litig.*, MDL No. 2804, as of the date of this notice.
4. “Prescription Opioids” means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in Ohio only through prescriptions filled by dispensers duly licensed and regulated.
5. “Illicit Opioids” means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted
6. “DEA Registrant” means Registrant as defined in 21 CFR 1300.01(b) (“any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act”).
7. “Chargeback Data” means information that a manufacturer receives from a distributor in connection with a chargeback, a contractual payment from a manufacturer to a distributor made after a distributor sells the manufacturer’s product to the distributor’s customer for less than the price the distributor paid the manufacturer for the product.
8. “Prescriber Data” means all information related to a person or entity that writes or has written a prescription as defined in 21 CFR. 1300.01(b) (“Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user...”).
9. “Suspicious Order Report” means a report filed by DEA Registrants pursuant to 21 CFR 1301.74(b).

10. "ARCOS Data" means data reported by DEA Registrants pursuant to 21 U.S.C. § 827 through the Automation of Reports and Consolidated Orders System.
11. "Opioid Production Quota" means the quantity of Prescription Opioids "necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks" per 21 C.F.R. 1303.11.
12. "Opioid Procurement Quota" means the quantity of Prescription Opioids that DEA allows a person or entity to "procure and use... for the purpose of manufacturing such class into dosage forms or into other substances per 21 CFR 1303.12.

TOPICS FOR EXAMINATION

The topics upon which the person or persons designated by You are asked to be prepared to testify in accordance with Rule 30(b)(6) are:

1. The organizational structure of the Office of Diversion Control and the Detroit Diversion Office, the Cleveland, OH Resident Office, the Youngstown, OH Resident Office, the Cleveland Tactical Diversion Squad, and any other unit or subunit of DEA with responsibilities in the state of Ohio.
2. Your interpretation and enforcement of, and practices related to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.
3. Guidance or other Communications provided by You to Defendants, whether written or oral, regarding the criteria for what makes an order for controlled substances "suspicious" under 21 C.F.R. § 1301.74.
4. Your involvement in lawsuits brought against DEA-registered distributors by customers whose orders of controlled substances had been blocked based on the distributor's determination that the orders were "suspicious" pursuant to 21 C.F.R. § 1301.74, or whose ability to purchase controlled substances had been denied or terminated.
5. Your interpretation, enforcement, and practices regarding any obligation to monitor orders placed with other third party registrants and/or the use or potential use of Chargeback Data in connection with any obligation under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.
6. The use or potential use of Prescriber Data in connection with any obligation under 21 U.S.C. § 823 and 21 C.F.R. § 1301.74.
7. Your efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.
8. Inquiries or complaints received by You from any government officials of the Ohio Board of Pharmacy, the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or

Cuyahoga County regarding Suspicious Order Reports, or suspected or actual diversion of Prescription Opioids.

9. Your procedures and practices relating to obtaining, processing, analyzing, and taking formal or informal actions based upon ARCOS Data, Suspicious Order Reports, or other Communications from DEA Registrants to identify and stop sources of diversion.
10. Investigations or inquiries by You concerning the Defendants.
11. Your practice of notifying DEA-registered distributors when another distributor terminated its relationship with a customer due to the risk of diversion, including DEA's decision to discontinue such practice.
12. Your decision not to allow DEA-registered distributors access to de-identified ARCOS Data prior to February 2018, and its decision to provide DEA-registered distributors with limited access to certain ARCOS Data in February 2018.
13. Your practices and procedures relating to the establishment of Opioid Procurement Quotas and Opioid Production Quotas for Prescription Opioids.
14. The basis for Opioid Procurement Quotas and Opioid Production Quotas of Prescription Opioids from 1995 to 2018.
15. Your procedures, process, approach, and criteria used to determine the legitimate medical, scientific, and industrial needs for Prescription Opioids and setting Opioid Production Quotas based upon those determinations.
16. Communications between You and any of the Defendants.
17. Communications between You and the Board of Pharmacy of any State, the Attorney General of any State, or government officials of the City of Cleveland, the City of Akron, Cuyahoga County (Ohio), or Summit County (Ohio), or any township, village, or city within Summit County or Cuyahoga County relating to Prescription Opioids or Illicit Opioids.
18. Your policies, procedures, practices, and experience regarding the sharing of ARCOS data with state and local law enforcement entities when requested by them in connection with investigations of or suspicions regarding possible diversion by DEA-registrants in their jurisdictions.
19. Your policies and procedures relating to the "High Intensity Drug Trafficking Areas" (HIDTA) program.
20. The HIDTA program's efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic in Summit County, OH; Akron, OH; Cleveland, OH; Cuyahoga County, OH; or any township, village, or city within Summit County or Cuyahoga County.

21. Your Communications relating to and efforts to comply with the reports and recommendations contained in the following GAO Reports:

- a. *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed: Coordination between DEA and FDA Should Be Improved*, GAO-15-202 (Washington, D.C.: February 2, 2015);
- b. *Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (Washington, D.C.: June 25, 2015);
- c. *Drug Enforcement Administration: Additional Actions Needed to Address Prior GAO Recommendations*, GAO-16-737T (Washington, D.C.: June 22, 2016).

22. Your expenditure of funds allocated to the Diversion Control Fee Account.

23. Your process for licensing prescribers of controlled substances.

24. Investigation into the retention or removal of documents by Joseph Rannazzisi, and any other former DEA employees currently retained by Plaintiffs.

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Ohio

In re National Prescription Opiate Litigation

Plaintiff

v.

Defendant

Civil Action No. 1:17-md-02804-DAP

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS
OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Drug Enforcement Administration, 8701 Morrisette Dr., Springfield, VA 22152

(Name of person to whom this subpoena is directed)

☒ **Production:** **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Schedule A and Case Management Order #2

Place: Williams & Connolly LLP, 725 Twelfth St. NW,
Washington, DC 20005

Date and Time:

07/31/2018 9:30 am

☐ **Inspection of Premises:** **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:

Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 07/10/2018

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

/s/ Enu Mainigi

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing (name of party)

All Defendants, who issues or requests this subpoena, are:

Enu Mainigi, 725 Twelfth St. NW, Washington, DC 20005, emainigi@wc.com, 202-434-5000

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

AO 88B (Rev. 02/14) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Page 2)

Civil Action No. 1:17-md-02804-DAP

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for (name of individual and title, if any) _____
on (date) _____.

☐ I served the subpoena by delivering a copy to the named person as follows: _____

_____ on (date) _____; or

☐ I returned the subpoena unexecuted because: _____

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____.

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)**(c) Place of Compliance.**

(1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
 - (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) Appearance Not Required. A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) Objections. A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) When Required. On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) When Permitted. To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

- (i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) Specifying Conditions as an Alternative. In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) Documents. A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) Form for Producing Electronically Stored Information Not Specified. If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) Electronically Stored Information Produced in Only One Form. The person responding need not produce the same electronically stored information in more than one form.

(D) Inaccessible Electronically Stored Information. The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) Information Withheld. A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) Information Produced. If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

SCHEDULE A

DEFINITIONS

Notwithstanding any definition set forth below, each word, term, or phrase used in these Requests is intended to have the broadest meaning permitted under the Federal Rules of Civil Procedure and the Local Civil Rules for the District Court of the Northern District of Ohio.

1. “You” and “Your” refers to the Drug Enforcement Administration (“DEA”) and all others acting or purporting to act on DEA’s behalf, including any employees, officers, committees, subcommittees, working groups, and joint task forces.
2. “Communication” means any transmission of information (whether formal or informal) by one or more Persons and/or between two or more Persons by means including, but not limited to, telephone conversations, letters, faxes, electronic mail, text messages, instant messages, other computer linkups, written memoranda, and face-to-face conversations.
3. “Defendants” means all defendants named in *In re National Prescription Opiate Litig.*, MDL No. 2804, as of the date of this notice.
4. “Document” has the full meaning ascribed to it by Federal Rule of Civil Procedure 34(a), and means the complete original (or complete copy where the original is unavailable) and each non-identical copy (where different from the original because of notes made on the copy or otherwise) of any writing or record, including, but not limited to, all written, typewritten, handwritten, printed, or graphic matter of any kind or nature, however produced or reproduced, any form of collected data for use with electronic data processing equipment, and any mechanical or electronic visual or sound recordings or text messages in Your possession, custody, or control. “Documents” include, but are not limited to, books, papers, contracts, memoranda, invoices, correspondence, notes, studies, reports, manuals, photographs, drawings, charts, graphs, data compilations, other writings, microfilm, microfiche, audio recordings, video recordings, electronic mail, and any other information stored in electronic form, and each different version or copy of each Document, including, but not limited to, drafts.
5. “Prescription Opioids” means FDA-approved pain-reducing medications that consist of natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body to produce an analgesic effect, including but not limited to prescription medications containing hydrocodone, oxycodone, fentanyl, and hydromorphone, that may be obtained by patients in Ohio only through prescriptions filled by dispensers duly licensed and regulated.
6. “Illicit Opioids” means substances comprised of or containing natural, synthetic, or semisynthetic chemicals that bind to opioid receptors in the brain or body that are not obtained from a licensed practitioner pursuant to a legitimate prescription. Illicit opioids include but are not limited to heroin, fentanyl, carfentanil, other fentanyl-type analogs, counterfeit opioid medications, and Prescription Opioids that are diverted.

7. “DEA Registrant” means Registrant as defined in 21 CFR 1300.01(b) (“any person who is registered pursuant to either section 303 or section 1008 of the [Controlled Substances] Act”).
8. “Registration” means Registration as defined in 21 CFR 1300.01(b) (“registration required and permitted by sections 303 or 1007 of the [Controlled Substances] Act”).
9. “Chargeback Data” means information that a manufacturer receives from a distributor in connection with a chargeback, a contractual payment from a manufacturer to a distributor made after a distributor sells the manufacturer’s product to the distributor’s customer for less than the price the distributor paid the manufacturer for the product.
10. “Prescriber Data” means all information related to a person or entity that writes or has written a prescription as defined in 21 CFR. 1300.01(b) (“Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user...”).
11. “Opioid Production Quota” means the quantity of Prescription Opioids “necessary to be manufactured during the following calendar year to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks” per 21 C.F.F 1303.11.
12. “Opioid Procurement Quota” means the quantity of Prescription Opioids that DEA allows a person or entity to “procure and use... for the purpose of manufacturing such class into dosage forms or into other substances per 21 CFR 1303.12.
13. “Suspicious Order Monitoring Program” means a system intended to aid in compliance with 21 CFR. 1301.74 as defined by DEA to be required by 21 CFR. 1301.74.

INSTRUCTIONS

Should You consider any of the Documents requested to be confidential such that they should not be generally disseminated to the public or released to the press, we ask that You designate them as such under the Protective Order in the MDL (copy attached) and the parties will deal with them accordingly.

All of the following requests are intended to encompass Documents maintained in electronic or paper form, and “correspondence” or “Communications” include emails, letters or other papers, and memos reflecting oral Communications.

As these Documents will be shared with a large number of counsel and parties, we ask that You produce copies of them in electronic or paper form. Please let the undersigned know if there are charges or fees for searching or copying and, if so, also advise whether You will provide an invoice for the cost after production or if prepayment is required.

Unless otherwise indicated, the Relevant Time Period applicable to these requests is 1996 to the present.¹

DOCUMENTS TO BE PRODUCED

1. All Documents concerning Communications between DEA and DEA Registrants regarding any actual or purported obligation under 21 U.S.C. § 823, 21 CFR 1301.74 or any other DEA regulation with respect to suspicious orders for controlled substances, including but not limited to letters, presentations, emails, conference materials, or other correspondence.
2. All Documents concerning DEA's ability or willingness to provide guidance to DEA Registrants regarding their obligations under 21 U.S.C. § 823, 21 CFR 1301.74, or any other DEA regulation with respect to suspicious orders for controlled substances.
3. All Documents concerning the meaning of the term "suspicious orders" in connection with orders for controlled substances, including but not limited to all Documents reflecting DEA's position regarding the meaning of "suspicious orders."
4. All Documents concerning any requirement or expectation that DEA Registrants inform DEA of suspicious orders not placed directly with the Registrant, such as orders exchanged between two third parties.
5. All Documents concerning the use or potential use of Chargeback Data in connection with any obligation under the CSA, 21 CFR 1301.74, or any other DEA regulation, including but not limited to all Documents regarding DEA's position on whether DEA Registrants had a legal duty to review such data.
6. All Documents concerning the use or potential use of Prescriber Data in connection with any obligation under the CSA, 21 CFR 1301.74, or any other DEA regulation, including but not limited to all Documents regarding DEA's position on whether DEA Registrants had a legal duty to review such data.
7. All Documents reflecting or related to DEA's position regarding any obligation of DEA Registrants to halt or not ship suspicious orders.
8. All Documents constituting or describing DEA's procedures, policies, or protocols regarding its receipt, organization, analysis, utilization, and handling of suspicious order reports received pursuant to 21 CFR 1301.74.
9. All Documents describing, relating to, or reflecting efforts made by DEA to utilize the ARCOS data, suspicious order reports, and/or other communications from Defendants to

¹ Defendants have asserted that discovery in this matter should be limited to the relevant statutes of limitations for Plaintiffs claims. Thus far, the Court has determined that the relevant time period goes back to at least 1996. Should the Court issue a ruling establishing a different time period for discovery, we will revise the Relevant Time period accordingly.

identify pharmacists, pharmacy interns, doctors or other prescribers, or patients who might be diverting controlled substances.

10. All Documents describing, relating to, or reflecting Defendants' efforts to obtain access to ARCOS data and/or suspicious order reports to identify pharmacists, pharmacy interns, doctors or other prescribers, or patients who might be diverting controlled substances including, but not limited to, all Documents describing, relating to, or reflecting the DEA's response to Defendants' efforts to obtain access to ARCOS data and/or suspicious order reports.
11. All DEA files and records relating to diversion or misuse of Prescription Opioids, including but not limited to the following:
 - a. Correspondence related to potential or actual diversion or misuse of Prescription Opioids;
 - b. Correspondence from or to any other Department of Justice agency or office (including but not limited to, any United States Attorney's Office), any other federal agency, any state agency, or any federal, state, or local official relating to the diversion or misuse of Prescription Opioids;
 - c. Complaints made to DEA relating to the diversion or misuse of Prescription Opioids, documents and correspondence reflecting any actions undertaken by DEA relating to such complaints, and any other records relating to such complaints;
 - d. Correspondence with any federal, state, or local agency regarding Suspicious Order reports.
12. All Documents concerning DEA's efforts to assess or track the illegal entry, distribution, or use of Prescription Opioids or Illicit Opioids in the state of Ohio.
13. Organizational charts and other Documents reflecting the structure and operations of the Office of Diversion Control, the Detroit Division Office, the Cleveland, OH Resident Office, the Youngstown, OH Resident Office, the Cleveland Tactical Diversion Squad, and any other unit or subunit of DEA with responsibilities in the state of Ohio.
14. All Documents concerning policies and procedures related to the "High Intensity Drug Trafficking Areas" (HIDTA) program, including Documents regarding the criteria and process involved in designation of a HIDTA.
15. All Documents concerning any and all HIDTAs in the state of Ohio, and all Documents concerning DEA operations, activities, or assistance related to any and all HIDTAs in the state of Ohio.
16. All Documents concerning Communications between DEA and any other Department of Justice agency or office, the Office of National Drug Control Policy, and any other federal agency regarding strategies and proposals to address the opioid crisis.

17. All Documents reflecting or relating to reports, inquiries, or complaints received from any government officials of the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, regarding suspicious order reports pursuant to 21 CFR 1301.74, or suspected or actual diversion or misuse of Prescription Opioids by TDDDs, pharmacists, pharmacy interns, doctors, other prescribers or dispensers, or patients.
18. All Documents and Communications with any federal, state, or local agency in or with jurisdiction over the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, regarding efforts to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic.
19. All Documents and Communications regarding any assistance or grants the DEA gave to any federal, state, or local agency in or with jurisdiction over the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, to combat diversion, respond to the Opioid epidemic, or form a joint task force to combat the Opioid epidemic.
20. All Documents and Communications with any federal, state, or local agency in or with jurisdiction over the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, and/or any distributor or manufacturer, regarding access to Suspicious Order reports and/or the DEA's ARCOS database.
21. All Documents or Communications concerning the DEA's efforts to investigate any pharmacists, pharmacy interns, doctors or other prescribers in the City of Cleveland, the City of Akron, Cuyahoga County, or Summit County, or any township, village, or city within Summit County or Cuyahoga County, prior to registering them or renewing their registration to lawfully prescribe or dispense controlled substances
22. All Documents and Communications concerning the determination of Opioid Production Quotas and Opioid Procurement Quotas.
23. All Documents concerning Communications with or about the Healthcare Distribution Alliance or Healthcare Distribution Management Association.
24. All Documents concerning Communications with or about the Government Accountability Office (GAO) relating to the following reports:
 - a. *Prescription Drugs: More DEA Information about Registrants' Controlled Substances Role Could Improve Their Understanding and Help Ensure Access*, GAO-15-471 (June 25, 2015).

- b. *Drug Shortages: Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved*, GAO-15-202 (February 2, 2015).
- c. *Additional Actions Needed to Address Prior GAO Recommendations*, GAO-16-737T (June 22, 2016).

- 25. All Communications or correspondence between DEA and any of the Defendants.
- 26. All Documents concerning Communications with or regarding the Defendants, including but not limited to Communications regarding their Suspicious Order Monitoring Program, the adequacy of Defendants' systems to safeguard against diversion, Quota, or Prescription Opioids.
- 27. All Documents or Communications concerning the DEA's desire to receive suspicious order reports, including any and all Documents or Communications in which the DEA told a manufacturer or distributor to stop submitting suspicious order reports.
- 28. All Documents concerning any visits by DEA personnel to any of Defendants' facilities, including but not limited to reports regarding audits and inspections, audit work papers, check sheets, and questions or inquiries concerning suspicious order monitoring, detecting, and reporting.
- 29. All Documents concerning the DEA registration of any of the Defendants, including but not limited to all Documents describing, relating to, or reflecting the revocation of Registration for any DEA Registrant relating to Prescription Opioids.
- 30. All Documents concerning any investigation or inquiry by DEA concerning the Defendants.
- 31. Documents concerning any efforts to address the diversion of Prescription Opioids in the state of Ohio.
- 32. All Documents concerning this civil action (captioned above) or any other lawsuit (regardless of whether criminal or civil, and regardless of whether brought or pending in state or federal court in the United States) relating to the diversion, overprescribing, or misuse of Prescription Opioids.
- 33. All Documents DEA has identified or determined were retained by Joseph Rannazzisi upon the conclusion of his employment with DEA, as well as all documents concerning DEA's investigation of whether documents were retained by Mr. Rannazzisi upon the conclusion of his employment with DEA.
- 34. The complete personnel file relating to the employment of Joseph Rannazzisi by the DEA.

35. All Documents DEA has identified or determined were retained by Jim Geldof upon the conclusion of his employment with DEA, as well as all documents concerning DEA's investigation of whether documents were retained by Mr. Rannazzisi upon the conclusion of his employment with DEA.
36. The complete personnel file relating to the employment of Jim Geldof by the DEA.
37. All Documents provided by the DEA or by any current or former employee of the DEA to the Washington Post and/or to 60 Minutes, and all Documents concerning DEA's investigation relating to Documents provided to the Washington Post and/or 60 Minutes.